

comprises a sparingly water-soluble drug that is crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

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canceled

Claim 46 has been canceled.

25 ~~22~~ (Once Amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;

comprises a sparingly water-soluble drug that is crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

Claim 48 has been canceled.

REMARKS

The above amendments have been made as the result of a telephone conversation between the undersigned Attorney, Examiner Fubara, and Dr. Bruce DeKock of Bend Research Inc. This document is being transmitted via fax to Examiner Blessing Fubara at 703-746-5013.

The claims have been amended to state that the solid dispersions recited as an element of the claims have a drug:polymer weight ratio of 1 to 0.2 to 1 to 100. Support is in the specification at page 13, lines 24-26.

Independent claims 39, 43, 45, and 47 additionally state that the sparingly water-soluble drug comprising the dispersion has a dose to aqueous solubility

ratio greater than 100. Support is at page 7, lines 17-19. Claims 40, 44, 46, and 47 have accordingly been canceled.

Other amendments have been made to improve form. For example, the phrase "of matter" has been introduced into the preamble of some independent claims so that all of the independent composition-of-matter claims use parallel wording in starting off with the phrase "A composition of matter".

No fee is thought to be due for this submission. If, however, the Commissioner determines that any fee is due, please charge it to Deposit Account No. 16-1445. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this sheet are enclosed.

Respectfully submitted,

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VERSION MARKED UP TO SHOW CHANGES MADE

1. (Three Times Amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;

comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and hydroxypropylmethylcellulose acetate succinate (HPMCAS),

~~said dispersion providing~~ provides a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

7. (Three Times Amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion

is homogeneous;

comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS,

~~said dispersion exhibiting~~ exhibits a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

11. (Twice Amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;

comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS,

~~said dispersion effecting effects~~, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

15. (Twice Amended) A composition of matter comprising a spray dried solid dispersion, which dispersion is homogeneous;

comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS,

~~said dispersion effecting effects~~, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

39. (Once Amended) A composition of matter comprising a spray dried solid dispersion, which dispersion is homogeneous;

comprises a sparingly water-soluble drug that is crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said dispersion providing a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

Claim 40 has been canceled without waiver or prejudice.

43. (Once Amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion is homogeneous;

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comprises a sparingly water-soluble drug that is crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion exhibiting a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

Claim 44 has been canceled without waiver or prejudice.

45. (Once Amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion
is homogeneous;

comprises a sparingly water-soluble drug, ~~said drug being that is~~ crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

Claim 46 has been canceled.

47. A composition of matter comprising a spray dried solid dispersion, which dispersion
is homogeneous;

comprises a sparingly water-soluble drug, ~~said drug being that is~~ crystalline when undispersed and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least

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1.25 relative to a control composition comprising an equivalent quantity of
undispersed drug; and

has a drug:polymer weight ratio of 1 to 0.2 to 1 to 100.

Claim 48 has been canceled.